

EXHIBIT S

Andrew N. Faes

From: Tom P. Cartmell
Sent: Sunday, June 02, 2013 9:56 AM
To: Andrew N. Faes; Joe Zonies; Gregory Bentley; Shea Shaver; Rich Freese; Renee Baggett; Brian Aylstock
Subject: Fwd: Scan file attached
Attachments: Scan.PDF; ATT00001.htm

Tom Cartmell

Begin forwarded message:

From: "Phil Combs" <PCombs@tcspllc.com>
To: "Tom P. Cartmell" <tcartmell@wcllp.com>
Cc: "Chad Hutchinson (Chad.Hutchinson@butlersnow.com)" <Chad.Hutchinson@butlersnow.com>
Subject: FW: Scan file attached

Tom: here is the chart that Dan Smith is going to use to testify from on the DHF issue.

As we discussed in the earlier e-mail we will be sending you a version that is formatted a little better & BSâ€™d prior to the deposition. Thank you for agreeing to switch them out.

One thing you might notice is that for some of the volumes of the TVT-O DHF, the BS range is not the same as the BS ranges for the ones Joe introduced into evidence. This DOES NOT mean that the dhf is different it is merely that Joe marked (for volume 1-6) a copy that wasnâ€™t the official copy but rather the copy from Dan Smithâ€™s custodial file. The document is the same and we can switch out the exhibits, change the chart, or do whatever is necessary to confirm that those are the same as the ones on the chart for volumes 1-6. Frankly, I think the easiest thing will be to just change the chart.

Phil

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6/1/2013

Pelvic Mesh Litigation: DHF and eDHF Collection and Production

DHF0000467			China IFU Outsert - 'Neuchatel' - TVT	An IFU containing simplified Chinese is required to meet AQSIQ importation requirements in China. The current supplementary outsert IFU will be updated to include simplified Chinese. This supplementary IFU will be applied as an outsert in the European Distribution Centre (before shipment to China). This IFU does not replace the primary IFU. This critical and urgent requirement of having an IFU with simplified Chinese is detailed through the Decree of the State Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) - No. 95.	TVT	eDHF Feb 2012	ETH.MESH.06697264 - ETH.MESH.06697453 ETH.MESH.06698883 - ETH.MESH.06698885	95
DHF0000578			TVT Introducer and Catheter Guide Manufacturing Change	The TVT Introducer and Catheter Guide is currently manufactured by Josef in Sweden. Josef will not be continuing the manufacture of these devices going forward. Erchinger out of Germany is now the prime candidate for new production for these devices.	TVT	eDHF Feb 2012	ETH.MESH.06697454 - ETH.MESH.06698119 ETH.MESH.06698624 - ETH.MESH.06698629 ETH.MESH.06698633 - ETH.MESH.06698653 ETH.MESH.06698663 - ETH.MESH.06698742 ETH.MESH.06698796 - ETH.MESH.06698803 ETH.MESH.06698813 - ETH.MESH.06698818 ETH.MESH.06698844 - ETH.MESH.06698851 ETH.MESH.06698860 - ETH.MESH.06698870 ETH.MESH.06698886 - ETH.MESH.06698964	95
DHF0000834			TVT Device IFU (Instruction for Use Revision)		TVT	eDHF June 2011	ETH.MESH.00218088 - ETH.MESH.00218100 ETH.MESH.00223778 - ETH.MESH.00223792 ETH.MESH.00748213 - ETH.MESH.00748278 ETH.MESH.01310426 - ETH.MESH.01310482 ETH.MESH.01589783 - ETH.MESH.01589826	5,14,19

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6/7/2013

Pelvic Mesh Litigation: DHF and eDHF Collection and Production

DHF0000719		GYNECARE Mini TVT-Q	TVT ABBREVO	TVT Abbrev	eDHF June 2011	ETH.MESH.00223588 - ETH.MESH.00223633 ETH.MESH.00223793 - ETH.MESH.00223799 ETH.MESH.00754439 - ETH.MESH.00754857 ETH.MESH.00759086 - ETH.MESH.00759158 ETH.MESH.01320389 - ETH.MESH.01320394 ETH.MESH.01413955 - ETH.MESH.01419738 ETH.MESH.01589884 - ETH.MESH.01590014 ETH.MESH.01591876 - ETH.MESH.01591913 ETH.MESH.01592339 - ETH.MESH.01592352 ETH.MESH.01592399 - ETH.MESH.01592433 ETH.MESH.01592438 - ETH.MESH.01592488 ETH.MESH.01592496 - ETH.MESH.01592686 ETH.MESH.01592696 - ETH.MESH.01592781 ETH.MESH.01592791 - ETH.MESH.01592877 ETH.MESH.01592881 - ETH.MESH.01593008 ETH.MESH.01593235 - ETH.MESH.01593458 ETH.MESH.01594249 - ETH.MESH.01594272 ETH.MESH.01594413 - ETH.MESH.01594444 ETH.MESH.02312660 - ETH.MESH.02313036 ETH.MESH.02604374 - ETH.MESH.02604408 ETH.MESH.02615220 - ETH.MESH.02615222 ETH.MESH.02615240 - ETH.MESH.02615240 ETH.MESH.06715145 - ETH.MESH.06715496	6, 14, 19, 24, 32, 35
DHF0000747		TVT Retropublic Refresh		TVT Exact	eDHF June 2011	ETH.MESH.00223634 - ETH.MESH.00223655 ETH.MESH.00223800 - ETH.MESH.00223828 ETH.MESH.00754858 - ETH.MESH.00755383 ETH.MESH.01419739 - ETH.MESH.01593254 ETH.MESH.01593459 - ETH.MESH.01593681 ETH.MESH.02313037 - ETH.MESH.02313042 ETH.MESH.06715497 - ETH.MESH.06715589	6, 14, 19, 24, 35
	25 1-3251	DH0729 TVT-AA (Abdominal Guides & Couplers) - Design Verifications and Validations.pdf		TVT-AA	DHF Feb 2011	ETH.MESH.02222657 - ETH.MESH.02223554	22
	25 1-3252	DH0729 TVT-AA (Abdominal Guides & Couplers) - Final DDSA.pdf		TVT-AA	DHF Feb 2011	ETH.MESH.02223555 - ETH.MESH.02225347	22
	25 1-3119	DH0522 Tension-Free Vaginal Tape - Abdominal Approach CE Mark Project.pdf		TVT-AA	DHF Feb 2011	ETH.MESH.02221701 - ETH.MESH.02222014	22
	25 1-323	DH0581 CE Mark of GYNECARE TVT - AA Kit.pdf		TVT-AA	DHF Feb 2011	ETH.MESH.02222437 - ETH.MESH.02222656	22
	25 1-321	DH0583 TVT AA Kit & TVT AA Tray (810041A & 810071J) Transfer from J-Pac, US to Ethicon SARL, Switzerland - Book 1 of 2.pdf		TVT-AA	DHF Feb 2011	ETH.MESH.02222015 - ETH.MESH.02222436	22
	25 1-3139	DH0569 Tension-Free Vaginal Tape (TVT - D) Disposable Introducer and Spacer - Gynecare.pdf		TVT-D	DHF Feb 2011	ETH.MESH.03878676 - ETH.MESH.03880729	43

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Pelvic Mesh Litigation: DHF and eDHF Collection and Production

	25-1-3118	DH0921	TVT-L Blue PROLENE Mesh Component(2).pdf		TVT-L	DHF Feb 2011	ETH.MESH.01316852 - ETH.MESH.01317179	19
	25-1-3118	DH0921	TVT-L Blue PROLENE Mesh Component.pdf		TVT-L	DHF Feb 2011	ETH.MESH.01317180 - ETH.MESH.01317507	19
	25-1-3118	DH0921	TVT-L Blue PROLENE Mesh Component.pdf		TVT-L	DHF Feb 2011	ETH.MESH.02608122 - ETH.MESH.02608449	32
	25-1-290	DH1019	Gynecare TVT-O Project Overview Memo, Flowchart, DHCC, Final Drawings, Regulation, Design - 1 of 7.pdf		TVT-O	DHF Feb 2011	ETH.MESH.00221997 - ETH.MESH.00222463	5
	25-1-291	DH1019	Gynecare TVT-Obturator Testing Development, Process Development, Design Verification - Book 2 of 12).pdf		TVT-O	DHF Feb 2011	ETH.MESH.01317769 - ETH.MESH.01318358	19
	25-1-292	DH1019	Gynecare TVT-O Biocompatibility Testing, Stability Testing, Packaging Assessment- Qualification - 3 of 7.pdf		TVT-O	DHF Feb 2011	ETH.MESH.00222464 - ETH.MESH.00222778	5
	25-1-293	DH1019	Gynecare TVT-Obturator Sterilization Validation - Book 4 of 7.pdf		TVT-O	DHF Feb 2011	ETH.MESH.01318359 - ETH.MESH.01318831	19
	25-1-294	DH1019	Gynecare TVT-Obturator Design Validation, Clinical Assessment, Design Reviews, Process Reviews, Design Transfer, Meeting - Book 5 of 7.pdf		TVT-O	DHF Feb 2011	ETH.MESH.00222779 - ETH.MESH.00223267	5
	25-1-295	DH1019	Gynecare TVT-Obturator Helical Passers + Winged Guide - Process Validation Strategy and Process Documentation - Book 6 of 7.pdf		TVT-O	DHF Feb 2011	ETH.MESH.01318832 - ETH.MESH.01319499	19
	25-1-296	DH1019	Gynecare TVT-O Medline (Plastic Tube and Mesh Attachment) - Process Validation Strategy and Process Documentation - 7 of 7.pdf		TVT-O	DHF Feb 2011	ETH.MESH.01319500 - ETH.MESH.01320123	19
DH00000110			TVT Obturator IFU Change	Make changes to text of instructions for Use (IFU) for TVT Obturator (TVT-O) to clarify but not change surgical instructions.	TVT-O	eDHF June 2011	ETH.MESH.00218079 - ETH.MESH.00218087 ETH.MESH.00747987 - ETH.MESH.00748021 ETH.MESH.00759077 - ETH.MESH.00759081 ETH.MESH.01309905 - ETH.MESH.01309983 ETH.MESH.01589788 - ETH.MESH.01589789 ETH.MESH.02312289 - ETH.MESH.02312299 ETH.MESH.00218079 - ETH.MESH.00218087 ETH.MESH.00747987 - ETH.MESH.00748021 ETH.MESH.00759077 - ETH.MESH.00759081 ETH.MESH.01309905 - ETH.MESH.01309983 ETH.MESH.01589788 - ETH.MESH.01589789 ETH.MESH.02312289 - ETH.MESH.02312299	5, 14, 19, 24

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8/1/2013

Pelvic Mesh Litigation: DHF and eDHF Collection and Production

DHF0000465			China IFU Outsert - Neuchatel - TVT-O	An IFU containing Simplified Chinese is required to meet ACSIQ Importation requirements in China. The current supplementary outsert IFU will be updated to include Simplified Chinese. This supplementary IFU will be applied as an outsert in the European Distribution Centre (before shipment to China). This IFU does not replace the primary IFU. This critical and urgent requirement of having an IFU with Simplified Chinese is detailed through the Decree of the State Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) - No. 95.	TVT-O	@DHF Feb 2012	ETH.MESH.06696844 - ETH.MESH.06697061 ETH.MESH.06698827 - ETH.MESH.06698829	95
DHF0000662			TVT-O Needle Material Change	The TVT-O needle material is changing from Finathene 6006 HDPE to Purrell PE GF4750 HDPE because the manufacture has discontinued production of the Finathene material.	TVT-O	@DHF June 2011	ETH.MESH.00754305 - ETH.MESH.00754433 ETH.MESH.01413117 - ETH.MESH.01413760 ETH.MESH.01592336 - ETH.MESH.01592338 ETH.MESH.01592353 - ETH.MESH.01592371 ETH.MESH.06714731 - ETH.MESH.06714745	14, 19, 95
DHF0000671			TVT-O Data Matrix Change	Change of product code datamatrix content by removing the end extra character on P18040;P10081 Tyvek Ltd, P18041;P10081L Tyvek Ltd and P18081;P1008L Carton.	TVT-O	@DHF June 2011	ETH.MESH.00748165 - ETH.MESH.00748184 ETH.MESH.01310362 - ETH.MESH.01310388 ETH.MESH.01589797 - ETH.MESH.01589799	14, 19
DHF0000842			MDO Revision 2007/47 - Neuchatel (TVT Obturator)	Update of the instructions for Use (IFU) for TVT Obturator, Proforma, Prolift, and Prolift 4M. These products are manufactured at ETHICON Srl, Neuchatel, Switzerland. This eDHF covers the requirement for ETHICON to update all IFUs relevant to the product lines with a Risk of Reuse statement (per Council Directive 2007/47).	TVT-O	@DHF June 2011	ETH.MESH.00218101 - ETH.MESH.00218102 ETH.MESH.00748279 - ETH.MESH.00748309 ETH.MESH.01310483 - ETH.MESH.01310577 ETH.MESH.01589677 - ETH.MESH.01589679	5, 14, 19

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Pelvic Mesh Litigation: DHF and eDHF Collection and Production

DHF0000120		TVT SECUR	Please reference the Table of Content for the TVT-5 TVT SECUR-e-DHF contained in COTHE80000457 for an index of documentation contained within this DHF as it relates to critical Design Control categories.	TVT-5	eDHF June 2011	6,14,19,24,95
					ETH.MESH.00223393 - ETH.MESH.00223585 ETH.MESH.00752859 - ETH.MESH.00753374 ETH.MESH.00759119 - ETH.MESH.00759119 ETH.MESH.00759159 - ETH.MESH.00759161 ETH.MESH.01407509 - ETH.MESH.01410087 ETH.MESH.01591914 - ETH.MESH.01592202 ETH.MESH.01592245 - ETH.MESH.01594412 ETH.MESH.01594445 - ETH.MESH.01594780 ETH.MESH.02312487 - ETH.MESH.02312659 ETH.MESH.06703947 - ETH.MESH.06708058 ETH.MESH.06716925 - ETH.MESH.06716930 ETH.MESH.06717050 - ETH.MESH.06717063 ETH.MESH.06717216 - ETH.MESH.06717225 ETH.MESH.06717623 - ETH.MESH.06717697 ETH.MESH.06717807 - ETH.MESH.06717814 ETH.MESH.06717931 - ETH.MESH.06717950 ETH.MESH.06717954 - ETH.MESH.06718174	

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04/20/13

Pelvic Mesh Litigation: DHF and eDHF Collection and Production

DHF0000319			TVT SECUR Cancelled Transfer to Sored / Drawing Update	<p>The TVT-S drawing update manifested itself from the now cancelled TVT Sored Transfer Project. Dimensional evaluations during the project resulted in some minor drawing updates to provide clarity while maintaining design intent. On the Release Wire drawing P20022 a JEB manufacturing JIG number was added to the notes section as well as a note locating the weld spot. On drawing P20020 a welded view was added for clarity to supplement a stamped view as well as (3) additional reference dimensions. Finally (2) non-critical tolerances (which are driven by referenced curvature angles) were slightly modified to aide in the manufacturability of the device. Also documented in Design History File (000319) is the JEB Process Change for the grinding of the TVT-Secur Release Wire Tip. This process change is transparent to the end user and requires no drawing modifications.</p>	TVT-S	eDHF June 2011	<p>ETH.MESH.00748059 - ETH.MESH.00748084 ETH.MESH.01310089 - ETH.MESH.01310116 ETH.MESH.01589668 - ETH.MESH.01589676 ETH.MESH.01589680 - ETH.MESH.01589690</p>	14, 19
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